Abane L, Antract P, et al. A comparison of patient-specific and conventional instrumentation for total knee arthroplasty: a multicentre randomised controlled trial. Bone Joint J 2015;97-B: 56-63

Design: randomized clinical trial

Purpose of study: to compare the effectiveness of patient-specific cutting guides (PSCG) versus conventional instrumentation in improving the postoperative coronal alignment in patients undergoing total knee arthroplasty (TKA)

Population/sample size/setting:

- 140 patients (88 women, 52 men, mean age 69) undergoing TKA in an orthopedic surgery department in Paris
- Inclusion criteria were age 18 to 85, with the ability to understand the requirements and with entitlement to social security
- Exclusion criteria were active or suspected sepsis, a previous TKA, the presence of hardware which could cause artifact on MRI, or any deformity which would require osteotomy around the joint at the time of TKA

Interventions:

- All patients had the same posterior-stabilized fixed-bearing cemented TKA with patellar resurfacing by six experienced arthroplasty surgeons
- Computer-generated randomization allocated patients to either PSCG (n=70) or conventional instrumentation (CI, n=70)
- PSCG group had MRI and a standing AP radiograph six weeks prior to the scheduled TKA, which were sent to the manufacturer of the PSCG system for processing and formulation of a surgical plan, including the planned level of resection and the alignment and size of the femoral and tibial components; the plan was reviewed and approved by the surgeon prior to the manufacture of the cutting blocks
    - The PSCG cutting blocks were used for the proximal tibial and distal femoral cuts, but the remaining cuts, including the anterior, posterior, and chamfer femoral cuts, were made with standard instrumentation
- In the CI group, intramedullary guidance was used for both tibial and femoral preparation, setting the intramedullary rod on the femoral side at 5° to 7° of valgus in order to achieve a femoral cut perpendicular to the mechanical axis of the femur
- All other aspects of the TKA procedure, including wound closure, tourniquet release, drains, prophylactic anticoagulation with low molecular weight heparin, and postoperative regime, were identical between the two groups

Outcomes:

- Followup standing AP films were done three months after TKA and were read by an independent observer who was blinded to the instrumentation used
- The radiographic outcomes focused on alignment in the frontal plane with pre-specified normal values for the various angles measured
    - The normal hip-knee-ankle (HKA) angle was expected to be 180°, with an HKA angle > 180° considered to be valgus, with values < 180° being considered varus
    - Other measured angles were the F angle (between the tangent connecting the distal condyles of the prosthesis and the mechanical axis of the femur) and the T angle (between the tangent to the prosthetic tibial baseplate and the mechanical axis of the tibia)
        - Both angles had an expected measurement of 90°; a T or F angle > 90° was considered valgus of the component and a value < 90° was considered varus
    - For these angles, a deviation > 3° was considered to represent an "outlier"
- The HKA, F, and T angles were statistically equal in the groups at followup
    - The mean HKA angle for the CI group was 178.9° and for the PSBC group it was 178.2°
    - The mean F angle for the CI group was 90.1° and for the PSBC group it was 88.6°
    - The mean T angle for the CI group was 89.1 ° and for the PBSC group it was 89.8°
    - For the HKA angle there were 22 outliers in the CI group and 19 outliers in the PBSC group
- Some additional outcomes were also measured and compared; the Knee Society and Oxford Knee Scores were also equal between groups at three months
- Mean operating time, mean blood loss, and mean length of hospital stay were also equal between groups

Author's conclusions:

- For patients undergoing TKA, the coronal plane angles at the knee joint were not influenced by the nature of the instrumentation used during surgery, whether that instrumentation was patient-specific cutting guides or conventional instrumentation
- The study was short-term and the results do not necessarily imply long-term equivalence of knee alignment after knee replacement
- There were measurements only in the coronal plane, and the axial alignment was not evaluated
- Operating time, blood loss, and clinical knee function at three months were also not influenced by the instrumentation used for TKA

- Patient-specific cutting guides do not provide better clinical, radiological, or resource consumption advantages over conventional instrumentation

Comments:

- As with other studies of the effect of instrumentation on coronal knee alignment, the mean angles are reported together with their ranges, but not with their standard deviations; this is an obstacle to any attempt to combine the measurements in a meta-analysis
- However, the number of patients in the study, and the very small differences in means in the reported angles, yield good evidence that the measured angles are very nearly equal, and that the number of “outliers” which deviate by more than 3 ° are equal whichever intra-operative instrumentation was used
- The main outcome measurement was blinded, even though the patients allocated to PSCG would have been aware of their group assignment due to the fact that they had to have pre-operative radiological studies to prepare the specific instrumentation which was to be used for their operations

Assessment: High quality RCT providing good evidence that in the setting of total knee arthroplasty, the mechanical alignment three months after surgery are not influenced by whether the instrumentation used for the operation was patient-specific or was conventional instrumentation